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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,850	08/25/2006	Kazuhiko Fujisawa	21089/0207151-US0	3799

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EXAMINER	
CHO, JENNIFER Y	
ART UNIT	**PAPER NUMBER**
1621	

MAIL DATE	DELIVERY MODE
06/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,850	FUJISAWA ET AL.	
	Examiner	Art Unit	
	JENNIFER Y. CHO	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *3-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is in response to Applicant's communication filed on 2/25/08.

Claims 1-10 are pending in this application. Claims 3-6 have been withdrawn.

Claims 7-10 have been newly added.

Claim Rejections – 35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being confusing, because of the "subsequently mixing the epoxy silane represented by the general formula (a1), the carboxylic acid represented by formula (a2), the metal salt of the carboxylic acid represented by formula (a2) and water" description for the process step. Applicant has not clearly differentiated this step. Clarification is requested.

Claim Rejections – 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no evidence in the record for the amended claim language of "subsequently mixing the epoxy silane represented by the general formula (a1), the carboxylic acid represented by formula (a2), the metal salt of the carboxylic acid represented by formula (a2) and water", at the time of filing the application.

Additionally, the suggested amendment to claim 1, adding "subsequently mixing the epoxy silane represented by the general formula (a1), the carboxylic acid represented by formula (a2), the metal salt of the carboxylic acid represented by formula (a2) and water" raises an issue of new matter. This amounts to a new concept that was not present at time of filing.

Claim Rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

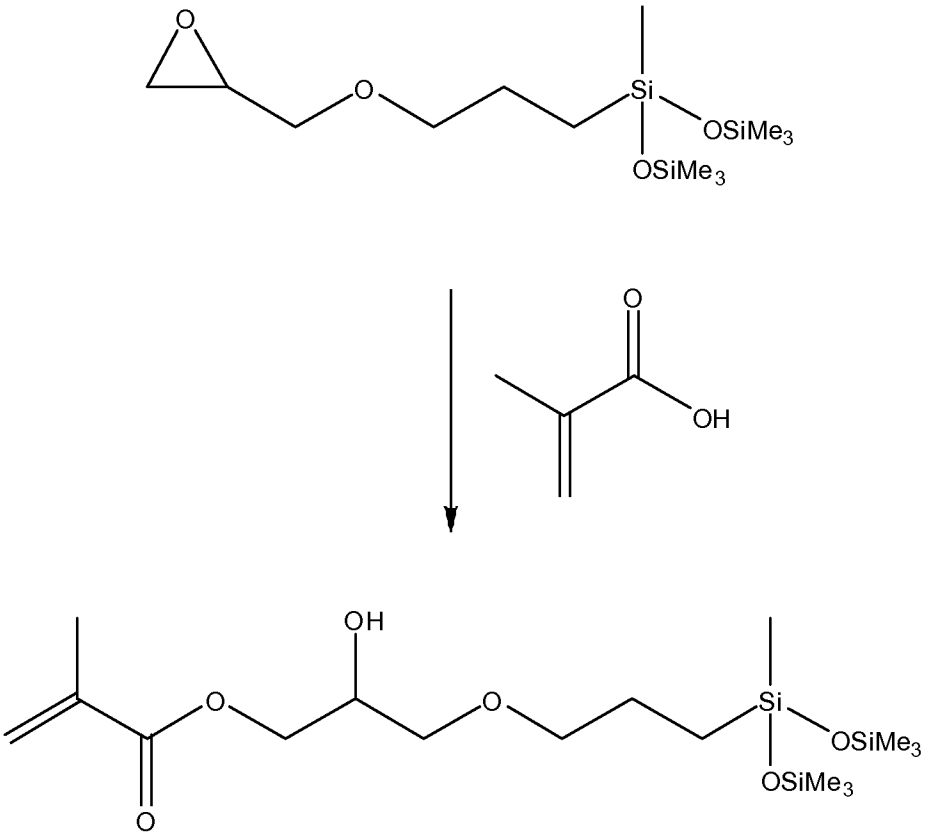
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (US 2004/0198916).

The instant claims are drawn to a process for producing a silicone compound by reacting a metal salt of the carboxylic acid with an epoxy silane, in the presence of 0.05 wt % or more of water.

Nakamura et al. teaches the following process, in which the metal salt of the carboxylic acid is formed in situ, by the addition of potassium hydroxide. The potassium salt of the acid reacts with the epoxy silane derivative to give the silicone product as shown below (page 6, section 67). In addition, ACS reagent grade potassium hydroxide contains 10-15% water, see printout[1].

[1] Sigma-Aldrich specification sheet for potassium hydroxide, ACS reagent grade.



The Examiner interprets the claim language of "subsequently mixing the epoxy silane represented by the general formula (a1), the carboxylic acid represented by formula (a2), the metal salt of the carboxylic acid represented by formula (a2) and water" to merely be mixing the epoxy silane and the carboxylic acid and/or salt in the reaction mixture. The carboxylic acid is in equilibrium with its metal salt and is pH dependent. Thus both the protonated and salt form of the carboxylic acid is expected to be present in the reaction solution. Therefore this claim is fully met.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (US 2004/0198916), in view of Inoue et al. (US 5,891,356).

The instant claims have been previously described.

The teaching of Nakamura et al. has also been previously described.

Nakamura et al. is deficient in that it does not explicitly state that the silicone product was purified by silica gel column chromatography and is silent as to the purity of the product.

With regard to the silicone purity and percentage of the compound represented by general formula (y), it is the position of the Examiner that one of ordinary skill in the art, at the time of the invention, would through routine and normal experimentation determine the optimization of these limitations to provide the best effective variable

depending on the results desired. Thus it would be obvious in the optimization process to optimize the purity of the silicone compound and to minimize impurity formation. The Applicant does not show any unusual and/or unexpected results for the limitations stated. Note that the prior art provides the same effect desired by Applicant, the production of silicone compounds for the ophthalmic lens industry.

Inoue et al. teaches the purification of a silicone compound by silica gel column chromatography (column 11, lines 48-49; column 14, lines 50-51).

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to use Inoue et al.'s purification method using silica gel column chromatography for Nakamura et al.'s process of making silicone compounds. One of ordinary skill in the art would be motivated to use column chromatography as a purification method with the reasonable expectation that the yield and purity of the product would increase. Absent any showing of unusual and/or unexpected results over applicant's particular purification method, the art obtains the same effect on the purity and yield of the silicone compounds. Furthermore, the limitations in some of the dependent claims, not expressly taught in the art, are also deemed to be obvious. One of ordinary skill in the art would be motivated to make fine adjustments and optimize these parameters to arrive at the instantly claimed invention. The expected result would be the efficient production of silicone compounds for the ophthalmic lens industry.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER Y. CHO whose telephone number is (571)272-6246. The examiner can normally be reached on 8:00 AM - 5:00 PM EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Cho
Patent Examiner
Art Unit: 1621

/SHAILENDRA - KUMAR/
Primary Examiner, Art Unit 1621